PATENT
Attorney Docket No: 03495-0008-08

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of)
)
Marc ALIZON et al.) Group Art Unit: 1648
)
Serial No.: 08/384,248) Examiner: J. PARKIN
)
Filed: February 6, 1995)
)
For: METHOD OF PRODUCING)
ANTIBODIES TO ANTIGENS)
OF HUMAN)
IMMUNODEFICIENCY)
VIRUS TYPE 1 (HIV 1))

Assistant Commissioner for Patents
Washington, D.C. 20231

APPEAL BRIEF

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APPELLANTS' BRIEF IN SUPPORT OF APPEAL

This is appellants' brief on appeal from the final rejection of claims (34), (35), and (36).

I. Real Parties in Interest

The real parties in interest are the assignees, Institut Pasteur and Centre National De La Recherche Scientifique, both of Paris, France, by virtue of a recorded assignment from the appellants.

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II. Related Appeals and Interferences

There are currently no other appeals and no interferences known to the appellants, the undersigned, or the assignees that will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. Status of Claims

The application as filed contained claims 1-22, all of which were canceled. Claim 23-33 were added during prosecution. Of these claims, claims 24-31 were subsequently canceled, and claims 23, 32, and 33 were finally rejected. Appellants filed a Notice of Appeal from the final rejection of claims 23, 32, and 33.

Appellants canceled claims 23, 32, and 33 after the Notice of Appeal was filed, and added claims 34, 35, and 36. These claims were entered for purposes of appeal.

A copy of claims 34, 35, and 36 can be found in the Appendix. No claims have been allowed.

IV. Status of Amendments

Appellants filed an Amendment after final on December 2, 1998, canceling claims 23, 32, and 33 and submitting new claims 34, 35, and 36. In the December 31, 1998, Advisory Action

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(Paper No. 36), the Examiner indicated that this Amendment would be entered and that claims 34, 35, and 36 were finally rejected.

V. Summary of the Invention

Appellants' invention relates to the discovery of cloned DNA sequences of the genome of Human Immunodeficiency Virus Type 1 and to the use of these sequences in the production of HIV-1 antigens and antibodies. The appealed claims are directed to methods of using the antigens to produce the antibodies.

HIV-1 was known at the time this application was filed. (Specification at 1, lines 9-13 and 23-29). Antigens of the virus and antibodies against the antigens are also known. Little was known, however, about the molecular biology of the virus. For example, the size of the viral genome was unknown. In addition, the locations of structural elements in the genome were unknown. Regions of the genome that encoded polypeptides that had antigenic properties were also unknown.

Against this backdrop of uncertainty, appellants were the first to create a recombinant molecular clone of HIV-1, which they designated λ-J19 (specification at 9, lines 31-35, and Fig. 2). The λ-J19 clone contained the genome of HIV-1, which

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appellants determined had a size of about 9100-9200 nucleotides. (Specification at 3, lines 18-21, and Fig. 2).[1]

It was appellants' belief that the λ-J19 clone represented the entire HIV-1 genome. (See specification at Fig. 2). Appellants' beliefs were subsequently validated, as illustrated by subsequent sequencing of this clone. *See* Wain-Hobson et al., *Cell* 40:9-17, Nucleotide Sequence of the AIDS Virus, LAV, 1985 (Exhibit 2 submitted with appellants' March 27, 1997, Amendment).

The λ-J19 clone enabled appellants to elucidate some of the structural features of the virus. (Specification at 9, lines 1-30). For example, appellants believed that the clone contained a gene encoding the envelope protein of the retrovirus. This gene was designated the *env* gene. Two other genes were believed to be in the clone; the *pol* gene, which encoded a retroviral polymerase, and the *gag* gene, which encoded a protein that comprises the core of the retrovirus.

Appellants discovered that the DNA in the λ-J19 clone contained several restriction sites that were related to the

---

[1]The λ-J19 clone was deposited at the Collection Nationale des Cultures de Micro-organismes (C.N.C.M.), a depository for biological material maintained by Institut Pasteur in Paris, France. (See specification at 14, lines 23-27).

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env, *pol*, and *gag* genes. (Specification at 3-4, bridging paragraph, and Fig. 2). Among the restriction sites were a *Kpn*I site at about 6100 and a *Bgl*II site at about 9150 of the λ-J19 clone. Appellants believed that the restriction fragment generated by cleavage of λ-J19 from this *Kpn*I site to the *Bgl*II site encoded at least part of the *env* gene of HIV-1. (Specification at 4, line 30, through page 5, line 2, and page 13, lines 16-19).

Appellants also discovered a *Kpn*I site at about 3500 and a *Bgl*II site at about 6500. Appellants believed that this restriction fragment encoded at least part of the polymerase of the HIV-1 *pol* gene. (Specification at 5, lines 3-5).

Finally, the λ-J19 clone contained a *Pst*I site at about 800 and a *Kpn*I site at about 3500. Appellants believed that this restriction fragment encoded at least part of the HIV-1 core, designated the *gag* gene. (Specification at 4, lines 6-9).

These three restriction fragments code for proteins and polypeptides, which are described in appellants' specification as sources of antigens and immunogens for diagnostic use and for use in vaccines. (Specification at 14, lines 1-4 and 13, lines 13-37). Appellants are claiming methods for the production of the antibodies to the HIV antigens and immunogens encoded by

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these three restriction fragments. Reference to the Appendix will show that one of these restriction fragments is recited in each of the claims on appeal.

VI. Issue

According to the Examiner, the "rejection is not based upon enablement considerations". (*See* Paper No. 34 at 3, lines 13-14). The Examiner concedes that the skilled artisan, at the time that the application was filed, provided with restriction fragments capable of encoding known antigens, could express and purify the antigens of interest and employ these antigens to generate antigen-specific antibodies.

Rather, the sole issue is whether the invention of claims 34, 35, and 36 is described in appellants' specification as required by 35 U.S.C. § 112, first paragraph.

VII. Grouping of Claims

The appealed ground of rejection is applicable to all of the claims on appeal. The claims stand or fall together.

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VIII. Argument

As characterized by the Examiner, "the crux of the matter is whether the skilled artisan, upon perusal of the disclosure, would reasonably conclude that applicants were in possession of the claimed invention." (Paper No. 37 at 2.) The claimed invention is, of course, a method of producing antibodies against an antigen encoded by one of the three restriction fragments. (See Appendix) It is the Examiner's belief that the specification fails to describe that the restriction fragments recited in the appealed claims encode the HIV-1 viral antigens, and that the specification fails to provide the coding potential of any of the claimed restriction fragments. The Examiner contends that the specification fails to provide an adequate written description of method steps involved in the production of viral antigens and virus-specific antibodies.

Appellants will conclusively show that they were in possession of the claimed methods for producing these antibodies.

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A. The specification literally describes the three restriction fragments recited in Claims 34, 35, and 36.

Appellants had possession of the three restriction fragments recited in the appealed claims because the fragments are literally described in the application.

Specifically, appellants created a restriction map of the λ-J19 clone by cleaving the cloned genome into fragments using restriction enzymes. (*See* specification at 3-4, bridging paragraph, and Fig. 2). Appellants literally described a nucleic acid restriction fragment extending from the *Kpn*I restriction site at about coordinate 6100 to the *Bgl*II restriction site at about coordinate 9150; they literally described a nucleic acid fragment extending from the *Kpn*I restriction site at about coordinate 3500 to the *Bgl*II restriction site at about coordinate 6500; and they literally described a nucleic acid fragment extending from the *Pst*I restriction site at about coordinate 800 to the *Kpn*I restriction site at about coordinate 3500. (Specification at 4, line 30, through page 5, line 9).

The Examiner asserted that "the disclosure does not provide the nucleotide sequence of any of these restriction fragments" (Paper No. 37 at 2-3). The claimed methods do not require

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knowledge of any of the nucleotide sequences to "describe" the antigens. Indeed, it is uncontested that the three restriction fragments recited in the appealed claims do, in fact, encode antigens of the *gag*, *pol*, and *env* genes. The antigens are adequately described by the restriction fragments that encode them.

These literal teachings satisfy the description requirement of § 112, first paragraph, for the three restriction fragments recited in the claims on appeal.

B. The specification literally describes proteins and polypeptides encoded by the three restriction fragments.

The appealed claims require "an antigen of . . .(HIV-1)". The HIV-1 proteins and polypeptides are prerequisites to the "antigen", and these proteins and polypeptides are literally described in the specification.

Appellants' specification begins with the statement that:

> The invention relates to cloned DNA sequences hybridizable Togenomic [sic, to genomic] RNA and DNA of lymphadenopathy-associated virus (LAV), a process for their preparation **and their uses.**

(Specification at 1, lines 4-7; emphasis added).

Among the "uses" referred to in this passage from the specification are the following:

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> b) DNA fragments corresponding to genes can be cloned into expression vectors for E. coli, yeast or mammalian cells and the resultant **proteins** purified.
>
> c) The provival DNA can be "shot-gunned" (fragmented) into procaryotic expression vectors to generate fusion **polypeptides**. Recombinant producing antigenically competent fusion **proteins** can be identified by simply screening the recombinants with antibodies against LAV antigens.

(Specification at 13, lines 25-33; emphasis added). Proteins and polypeptides are thus literally described in appellants' specification.

Appellants even claimed the means for obtaining these proteins and polypeptides in their original claims:

> 21. A microorganism, eucaryotic or procaryotic cell which is transformed by a vector according to claim 19 or 20 and which expresses the **polypeptide** encoded by the corresponding DNA fragment.

(Specification at 21, lines 13-16; emphasis added. Claims 19 and 20 referred to in this passage relate to expression vectors).

These literal recitations provide the descriptive prerequisites for the proteins and polypeptides needed to make antigens used in the methods claimed by appellants.

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C. The specification literally describes a need for antibodies against the HIV-1 proteins and polypeptides of the invention.

Appellants' description of the HIV-1 proteins and polypeptides encoded by the three restriction fragments must be considered in context: They are useful as antigens in diagnostic tests and as components of a vaccine against HIV-1. (Specification at 13, lines 13-16, "The DNA according to the invention can be used also for achieving the expression of LAV viral antigens for diagnostic purposes as well as far [sic, for] the production of a vaccine . . . .")

Before the proteins and polypeptides can be used for these purposes, however, they must be identified in the expression system, such as the cells of original claim 21 where they can be expressed. Appellants' specification literally describes how to identify the proteins and polypeptides:

> Recombinant producing [sic, Recombinantly produced] antigenically competent fusion proteins can be identified by simply screening the recombinants with **antibodies** against LAV antigens.

(Specification at 13, lines 30-33; emphasis added).

This teaching establishes a need for antibodies in order to realize one of appellants' goals: The isolation of antigenically competent proteins for use as HIV-1 antigens.

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D. The specification literally describes the use of the proteins and polypeptides of the invention as HIV-1 antigens.

The appealed claims recite "providing an antigen of HIV-1" encoded by one of the three restriction fragments. These antigens of HIV-1 are literally described in the specification.

For example, cloning of DNA fragments of the HIV-1 genome into expression vectors, expressing the DNA, and purifying the resulting proteins were contemplated by appellants as evidenced by the following passage from the specification:

> b) DNA fragments corresponding to **genes** can be cloned into expression vectors for E. coli, yeast- or mammalian cells and the resultant **proteins** purified.

(Specification at 13, lines 25-27; emphasis added). The "proteins" are antigens of HIV-1, and the "genes" encoding these antigens, of course, include the core (gag) gene, the envelope (env) gene, and the polymerase (pol) gene discussed on pages 4-6, *supra*.

Appellants even literally described HIV-1 viral antigens from the fragments encoding the core and the envelope proteins:

> The DNA according to the invention can be used also for achieving the expression of LAV **viral antigens** for diagnostic purposes as well as far [sic, for] the production of a vaccine against LAV. Of particular advantage in that respect are the DNA fragments coding **core** (gag region) and for **envelope**

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proteins, particularly the DNA fragment extending from Kpn I (6 100) to BglII(9 150).

(Specification at 13, lines 13-19; emphasis added).

The Examiner's assertion that "the disclosure does not teach that the claimed restriction fragments encode the viral antigens of interest" (Paper No. 37 at 2) simply does not withstand analysis against these teachings. Similarly, the Examiner's contention that "the coding potential of these restriction fragments are [sic, is] not readily manifest" (Id.) is without merit.[2]

---

[2]The contention that the "disclosure fails to provide a suitable written description of method steps involving the production of an antigen from said restriction fragments" (Paper No. 37 at 3) collapses in view of the following description of several methods that can be used to produce the antigens:

> "a) DNA can be transfected into mammalian cells with appropriate selection markers by a variety of techniques, calcium phosphate precipitation, polyethylene glycol, protoplast-fusion, etc.
>
> b) DNA fragments corresponding to genes can be cloned into expression vectors for E. coli, yeast- or mammalian cells and the resultant proteins purified.
>
> c) The provival [sic, proviral] DNA can be "shotgunned" (fragmented) into procaryotic expression vectors to generate fusion polypeptides. Recombinant producing [sic, recombinantly produced]antigenically competent fusion proteins can be identified by simply screening the recombinants with antibodies against LAV antigens.

(continued...)

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In essence, then, the three restriction fragments recited in the appealed claims are literally described in the specification, the proteins and polypeptides of HIV-1 encoded by these restriction fragments are literally described in the specification, use of the proteins and polypeptides as antigens is literally described in the specification, and the need for antibodies that recognize these antigens is literally described in the specification. This leaves only the step of "raising antibodies against said antigen," a recitation that is found in each of the appealed claims. The essence of this appeal, then, is whether appellants conveyed to a person of ordinary skill in the art that they were in possession of this step.

E. The step of "raising antibodies" recited in Claims 34, 35, and 36 is embodied in appellants' disclosure of the use of the HIV-1 proteins and polypeptides as "antigens".

Methods of using antigens to raise antibodies were well known in the art at the time of appellants' invention. The Examiner does not dispute that the appealed claims are enabled

---

[2](...continued)

d) The invention also relates to oligopeptides deduced from the DNA sequence of LAV antigen-genes to produce immunogens and antigens and which can be synthethized [sic, synthesized] chemically."

(Specification at 13, lines 13-37).

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by these methods or that a person of ordinary skill in the art would have had no difficulty "raising antibodies" against the antigens encoded by the three restriction fragments. It should also have been beyond dispute that the specification adequately describes the step of "raising antibodies".

Specifically, the specification teaches that the HIV-1 proteins and polypeptides of the invention can be used as antigens:

> All of the above (a-d) [see footnote 2, *supra*] can be used in diagnostics as sources of immunogens or **antigens** free of viral particles, produced using non-permissive systems, and thus of little or no biohazard risk.

(Specification at 14, lines 1-4; emphasis added). Use of "[a]ll of the above . . . as . . . antigens" in this quotation, of course, includes the use of all of the proteins and polypeptides of the invention as antigens.

The principal function of the immune system is to protect animals from infectious organisms and toxic substances. Immunity in animals is mediated by antibodies that are raised in response to exposure of the animal to the antigen. That is, by its very nature, an antigen involves the production of antibodies that bind to it; expressed another way, an antigen can be used to raise antibodies to itself.

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The written description requirement of §112 has been interpreted to require an applicant to convey with "reasonable clarity" to those skilled in the art that, as of the filing date, he or she was in possession of the invention. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1564, 19 U.S.P.Q. 2d 1111, 1117, (Fed. Cir. 1991). When the original specification accomplishes that conveyance, regardless of how it accomplishes it, the essential goal of the description requirement is realized. In re Wright, 866 F.2d 422, 424, 9 U.S.P.Q. 2d 1649, 1651 (Fed. Cir. 1989).

Appellants' description of the HIV-1 polypeptides encoded by the three restriction fragments as "antigens" accomplishes the essential goal of establishing that a person skilled in the art would have recognized with the "reasonable clarity" mandated by the Vas-Cath case that appellants were in possession of the HIV-1 antigens of the invention. The skilled person also would have recognized with "reasonable clarity" from appellants' specification that they possessed a need for antibodies to the antigens. Furthermore, the skilled artisan would have recognized with "reasonable clarity" that appellants were in possession of all of the techniques required to raise these

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antibodies, because it is conceded that these techniques were old in the art.[3]

In view of appellants' discovery of HIV-1 antigens and the admittedly old techniques for using them, it is unimaginable that a person skilled in the art would not have recognized with "reasonable clarity" that appellants contemplated "raising antibodies against said antigens", particularly in view of appellants' avowed need for these antibodies. This disclosure is sufficient to warrant reversal of the rejection.

F. Description of the use of the proteins and polypeptides as "immunogens" resolves any doubt that the specification describes the step of "raising antibodies".

Having established that the three restriction fragments encode antigens and having established a need for antibodies against these antigens, any doubt that may remain as to the adequacy of appellants' disclosure to support claims to the production of the antibodies is resolved by the following passage from appellants' specification:

---

[3]The Examiner stated: "The Examiner does not dispute the scientific findings that the skilled artisan, at the time of filing, provided with a restriction fragment capable of encoding a known antigen, could express and purify the antigen of interest and employ this protein to generate antigen-specific antibodies." (Paper No. 34 at 3, lines 14-18).

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> All of the above (a-d) [see footnote 1, *supra*] can be used in diagnostics as sources of **immunogens** or antigens free of viral particles, produced using non-permissive systems, and thus of little or no biohazard risk.

(Specification at 14, lines 1-4; emphasis added).

It is true that the passage quoted above does not literally duplicate the language of the appealed claims; that is, the passage does not literally recite "raising antibodies against said antigen" of HIV-1. Nevertheless, it is not necessary that the application describe the claim limitations exactly, but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including those limitations. In re Wertheim, 541 F.2d 257, 265, 191 U.S.P.Q. 90, 98 (C.C.P.A. 1976). How a teaching is set forth, by specific example or broad terminology, is not important. In re Marzocchi, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971).

The passage quoted above unequivocally indicates that the antigens of appellants' inventions are useful as sources of "immunogens". An "immunogen" is a molecule that is used to induce "immunity" in an animal when the animal is exposed to it. The immunogen is said to have "immunogenicity" in these circumstances. But immunogenicity is not an intrinsic property

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of any molecule. Rather, it is defined only by its ability to raise an adaptive response in the animal. As a result, adaptive immunity in the animal is directed against a specific molecule after exposure of the animal to the molecule.

Adaptive immunity is mediated by cells called lymphocytes, which synthesize cell surface receptors or secrete proteins that bind specifically to foreign molecules. These secreted proteins are known as "antibodies". Simply stated, a molecule "raises antibodies" to itself when it is used as an "immunogen".

The assertion that "the disclosure fails to provide a suitable written description of . . . raising antibodies against antigens" (Paper No 37 at 3) is without merit. The method step recited in each claim is "raising antibodies" (see Appendix). No other steps are required. Thus, the focus of the inquiry is whether the specification describes "raising antibodies."

Reading in appellants' application that the HIV-1 antigens encoded by the three restriction fragments are useful as "immunogens", knowing that immunogens are characterized in the art of immunology by their ability to induce adaptive immunity in an animal, and recognizing that adaptive immunity in the animal involves "raising antibodies," it should be apparent that appellants conveyed with much more than the "reasonable clarity"

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prescribed by the Vas-Cath case that they contemplated administering the antigens to an animal to raise antibodies, and thus were in possession of the claimed method step of "raising antibodies against said antigen", particularly when appellants established a need for the antibodies in their specification. The rejection should be reversed for this additional reason.

IX. Conclusion

The rejection of the claims under 35 U.S.C. § 112, first paragraph, on the ground of lack of an adequate written description is in error. Reversal of the rejection is respectfully requested.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Date: September 27, 1999

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APPENDIX

The claims on appeal are as follows:

34. A method of producing antibodies to an antigen of human immunodeficiency virus type 1 (HIV-1), said method comprising:

(a) providing an antigen of HIV-1, wherein said antigen is encoded by a nucleic acid fragment extending from the restriction site *Kpn*I at about coordinate 6100 to the restriction site *Bgl*II at about coordinate 9150 of plasmid λ-J19; and

(b) raising antibodies against said antigen.

35. A method of producing antibodies to an antigen of human immunodeficiency virus type 1 (HIV-1), said method comprising:

(a) providing an antigen of HIV-1, wherein said antigen is encoded by a nucleic acid fragment extending from the restriction site *Kpn*I at about coordinate 3500 to the restriction site *Bgl*II at about coordinate 6500 of plasmid λ-J19; and

(b) raising antibodies against said antigen.

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36. A method of producing antibodies to an antigen of human immunodeficiency virus type 1 (HIV-1), said method comprising:

(a) providing an antigen of HIV-1, wherein said antigen is encoded by a nucleic acid fragment extending from the restriction site *Pst*I at about coordinate 800 to the restriction site *Kpn*I at about coordinate 3500 of plasmid λ-J19; and

(b) raising antibodies against said antigen.

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